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VENABLE LLP			EXAMINER	
P.O. BOX 34385			VU, JAKE MINH	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEFFEN HASENZAHL,
JURGEN MEYER, and JURGEN HEYM

Appeal 2009-009246¹
Application 10/281,223
Technology Center 1600

Decided: March 15, 2010

Before LORA M. GREEN, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 5, 7-10, 12, and 13. We have jurisdiction under 35 U.S.C. § 6(b).

¹ Oral Hearing held March 9, 2010.

STATEMENT OF THE CASE

Claims 1 and 10 are representative of the claims on appeal, and read as follows:

5. A pharmaceutical composition comprising granular pyrogenically produced silicon dioxide, having void volumes, and at least one pharmaceutical active constituent, wherein the granular silica dioxide has meso-and macropores, a mean grain diameter of 10 to 120 μm and a BET surface of 40 to 400 m^2/g , determination according to DIN 66 131 using nitrogen, wherein the mesopores account for 10 to 80% of the total volume and the particle size distribution of the granular material is 80 vol. % greater than 8 μm and 80% less than 96 μm and the proportion of the pores less than 5 μm be at most 5% referred to the total pore volume.

10. An adsorbate comprising granular pyrogenically produced silicon dioxide, having void volumes, and absorbed on a surface and/or incorporated within the void volumes, at least one further substance selected from pharmaceutical active constituents and auxiliary substances, wherein the granular silicon dioxide has meso- and macropores, a mean grain diameter of 10 to 120 μm and a BET surface of 40 to 400 m^2/g , determination according to DIN 66 131 using nitrogen and the mesopores account for 10 to 80% of the total volume and the particle size distribution of the granular material is 80 vol. % greater than 8 μm and 80% less than 96 μm and the proportion of the pores less than 5 μm be at most 5% referred to the total pore volume, and wherein the adsorbate is prepared by forming a mixture by melting the substance(s) to be adsorbed, selected from pharmaceutical active constituents and auxiliary substances, or dissolving or dispersing the substance in a solvent; adsorbing the substance(s) by mixing the granular pyrogenically produced silicon dioxide with the mixture; and removing the solvent, when present.

The Examiner relies on the following evidence:

Hill	US 3,946,110	Mar. 23, 1976
Deller	US 5,776,240	Jul. 7, 1998

We reverse.

ISSUE

Has the Examiner provided a sufficient reason to combine Hill with Deller in establishing the obviousness of the claimed composition?

FINDINGS OF FACT

FF1 According to the Specification:

The present invention relates to the use of granular materials of pyrogenic silicic acid in pharmaceutical compositions. The granular materials are used in this connection in particular as carriers of pharmaceutical active constituents and/or auxiliary substances.

(Spec. 1.)

FF2 The Specification teaches further:

The advantages of the granular materials based on pyrogenically produced silicon dioxide compared to the known non-granulated pyrogenic silicic acids lie above all in the higher bulk density and tamped density, improve flowability, narrower grain size distribution, and dust-free processing. In addition tablets produced therefrom have a higher mechanical stability and an improved disintegration behaviour [sic].

(*Id.* at 23-24.)

FF3 The Examiner rejects claims 5, 7-10, 12, and 13 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Hill and Deller.

(Ans. 3.)

FF4 The Examiner relies on Hill for teaching a composition comprising pyrogenically produced silicon dioxide, such as Cab-O-Sil; at least one pharmaceutically active constituent; and at least one pharmaceutically active auxiliary substance, such as a lubricant. (*Id.*)

FF5 According to the Examiner, Hill teaches using silica dioxide is a pharmaceutical carrier. (*Id.* at 5.)

FF6 Hill “relates to improvements in analgesic and antifebritic or antipyretic compositions, improvements in tablets containing solid medicaments, and in methods of preparing such compositions and tablets.” (Hill, col. 1, ll. 11-15.)

FF7 Hill teaches compositions containing a combination of the acetylsalicylic acid with plant hydrocolloids, such as pectins, alginates, and carrageenin. (*Id.* at col. 4, ll. 59-62.) Hill teaches that in producing such combinations, it has been found that for best results, some water is required. (*Id.* at col. 4, ll. 61-67.)

FF8 Hill teaches that in producing the above combinations, lumping can occur. (*Id.* at col. 5, ll. 8-16.) According to Hill, however, such lumping can be reduced and substantially eliminated by adding to an original mixture of plant hydrocolloid and acetylsalicylic acid up to 10% of its weight of water-absorbing materials such as starches, clays, silica gel, and especially finely divided siliceous materials such as a silicon dioxide known as “Cab-O-Sil.”

(*Id.* at col. 5, ll 17-23.)

FF9 As to the “Cab-O-Sil,” Hill teaches:

“Cab-O-Sil” (made by Godfrey L. Cabot, Inc.) is a colloidal, submicronic or submicroscopic, pyrogenic silica prepared in a hot, gaseous environment by a vapor-phase, flame hydrolysis, at high temperature (1100° C.), of a silicon compound, such as silicon tetrachloride. It is distinct from silica gel obtained by precipitating silicic acid from an aqueous silicate solution, and hardening of the precipitate. Silica gel, thus formed, is internally porous. “Cab-O-Sil” has enormous external surface area and no internal porosity and contains no water-soluble

inorganic salts. It is of high chemical purity, low water content, a high degree of particle separation, and the particles are almost spherical in shape. One grade (designated as M-5) of "Cab-O-Sil" has a particle size range of 0.015 to 0.020 micron, and a surface area of substantially 175 to 200 square meters per gram. A finer grade (hereinbelow designated as H-5) has a particle size range of 0.007 to 0.010 micron, and a surface area of substantially 325 square meters per gram.

(*Id.* at col. 5, ll. 23-42.)

FF10 The Examiner notes that Hill "does not teach the physical property of the pyrogenic silicon dioxide." (Ans. 3.)

FF11 The Examiner relies on Deller for teaching a pyrogenically prepared silicon dioxide that has the properties of the claimed pyrogenically prepared silicon dioxide. (*Id.*)

FF12 Deller teaches granules based on silicon dioxide and that have the properties required by the claims. (Deller, Abstract.) According to Deller, the granules can be used as catalyst supports. (*Id.*)

FF13 Deller teaches:

The granular material according to the present invention can be prepared by dispersing pyrogenically prepared silicon dioxide in water, spray drying it and heating the granules obtained at a temperature of from 150° to 1,100° C. for a period of 1 to 8 hours.

Alternatively, the granular material according to the present invention can be prepared by dispersing pyrogenically prepared silicon dioxide in water, spray drying it and silanizing the granules obtained. Halosilanes, alkoxy silanes, silazanes and/or siloxanes can be used for the silanization.

(*Id.* at col. 1, l. 63-col. 2, l. 5.)

FF14 Deller specifically teaches that the granules may “be used as supports for polymerization catalysts, in particular as supports for catalysts for the production of polyethylene.” (*Id.* at col. 6, ll. 20-22.)

FF15 The Examiner concludes that it would have been obvious at the time of invention to incorporate the pyrogenic silicon dioxide particles of Deller into the composition of Hill because both Deller and Hill teach pyrogenic silicon dioxide, and pyrogenic silicon dioxide is used widely in the pharmaceutical industry. (Ans. 4.)

PRINCIPLES OF LAW

As the Supreme Court pointed out in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” Rather, the Court stated:

[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does . . .* because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id. at 418-419 (emphasis added); *see also id.* at 418 (requiring a determination of “whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue”) (emphasis added).

ANALYSIS

Appellants argue that Hill teaches a pharmaceutical composition that uses “Cab-O-Sil” in an amount to prevent lumping of the composition. (App. Br. 6.) Specifically, Appellants assert, Hill teaches that in formulating the pharmaceutical composition, lumping can occur, and that in order to prevent lumping, a water absorbing material, such as “Cab-O-Sil,” may be added. (*Id.*)

Deller, Appellants assert, does not remedy the deficiencies of Hill, as Deller discloses granules based on silicon dioxide that can be used as a support for a catalytically active substance that is capable of polymerizing ethylene to form polyethylene. (*Id.* at 7.) Appellants argue that Deller does not make any mention of pharmaceutical compositions, nor do they mention a pharmaceutical utility for their granular silica. (*Id.*) Thus, according to Appellants, “[t]he references are not properly combinable since there is no apparent problem in Hall [] for which Deller [] suggests a solution.” (*Id.*) Moreover, Appellants argue, the Examiner appears to be relying on improper hindsight to combine the references to arrive at the claimed composition. (*Id.* at 8.)

We agree with Appellants that the Examiner has not provided an adequate reason as to why the ordinary artisan would have used the granular silica of Deller instead of the “Cab-O-Sil” used in the pharmaceutical composition of Hill. As noted by Appellants, Hill teaches a water absorbing material, such as “Cab-O-Sil,” a pyrogenic silica. (See FF9.) Deller uses a pyrogenic material as a starting material (see FF13) to obtain granules based on silicon dioxide that may be used as a support for a catalyst, for example

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for use in the production of polyethylene. The Examiner has provided no evidence that the ordinary artisan would expect the granular silicon dioxide of Deller to have the same water absorbent properties as the "Cab-O-Sil" used in the pharmaceutical composition of Hill. Thus, we are compelled to reverse the rejection.

CONCLUSION OF LAW

We conclude that Examiner has not provided a sufficient reason to combine Hill with Deller in establishing the obviousness the obviousness of the claimed composition.

We thus reverse the rejection of claims 5, 7-10, 12, and 13 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Hill and Deller.

REVERSED

cdc

VENABLE LLP
P.O. BOX 34385
WASHINGTON DC 20043-9998